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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/660,812	09/12/2000	Kenny L. Dang	ACS 54573 (23111)	8165

7590 10/02/2002

Fulwider Patton Lee & Utecht LLP
Howard Hughes Center
Tenth Floor
6060 Center Drive
Los Angeles, CA 90045

EXAMINER

CHATTOPADHYAY, URMI

ART UNIT PAPER NUMBER

3738

DATE MAILED: 10/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/660,812

Applicant(s)

DANG ET AL.

Examiner

Urmi Chattopadhyay

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 7-9, 11-24, 26, 27 and 29-40 is/are pending in the application.
- 4a) Of the above claim(s) 5, 11-13, 24 and 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 7-9, 14-23, 26, 27, 29 and 33-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 14 June 2002 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The Amendment filed 6/14/02 has been entered as Paper No. 8. Claims 6, 10, 25 and 28 have been canceled and 1, 7, 9, 14, 16, 18, 20, 26-27, 33, 35 and 37 have been amended. Changes to the drawings have been approved by the Examiner.

2. On page 5 of the Amendment and Response, applicant indicates that (1) the title of the invention has been changed to one that is more descriptive, and (2) page 12, lines 13-15 of the specification have been amended to make it more consistent with Figure 4.

✓ These two changes have not been made because there was no indication to make the changes through an amendment, such as: --Please amend the title as follows:-- and --Please amend page 12, lines 13-15 as follows:--. In order to make these changes, Examiner suggests making them in the form of an amendment, including a clean and marked-up version of the changes in response to this office action.

Specification

✓ 3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

✓ 4. The disclosure is objected to because of the following informalities: it appears that page 12, lines 13-15 is incorrect, according to Figure 4, which shows opposite of what is stated. Figure 4 shows that the proximal end 26 of second section overlaps the distal end 22 of the first section 21.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 16, 29 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- ✓ 6. Claims 16 and 35 are indefinite for claiming subject matter not supported in the specification. PTFE is not mentioned in the specification for being a cover material option. It appears that PTFE should be PET.

- ✓ 7. Claim 29 is indefinite because it is currently depending from claim 28, which was canceled by the amendment. It appear claim 29 should be dependent on claim 27 and will be interpreted to be so for examination purposes.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

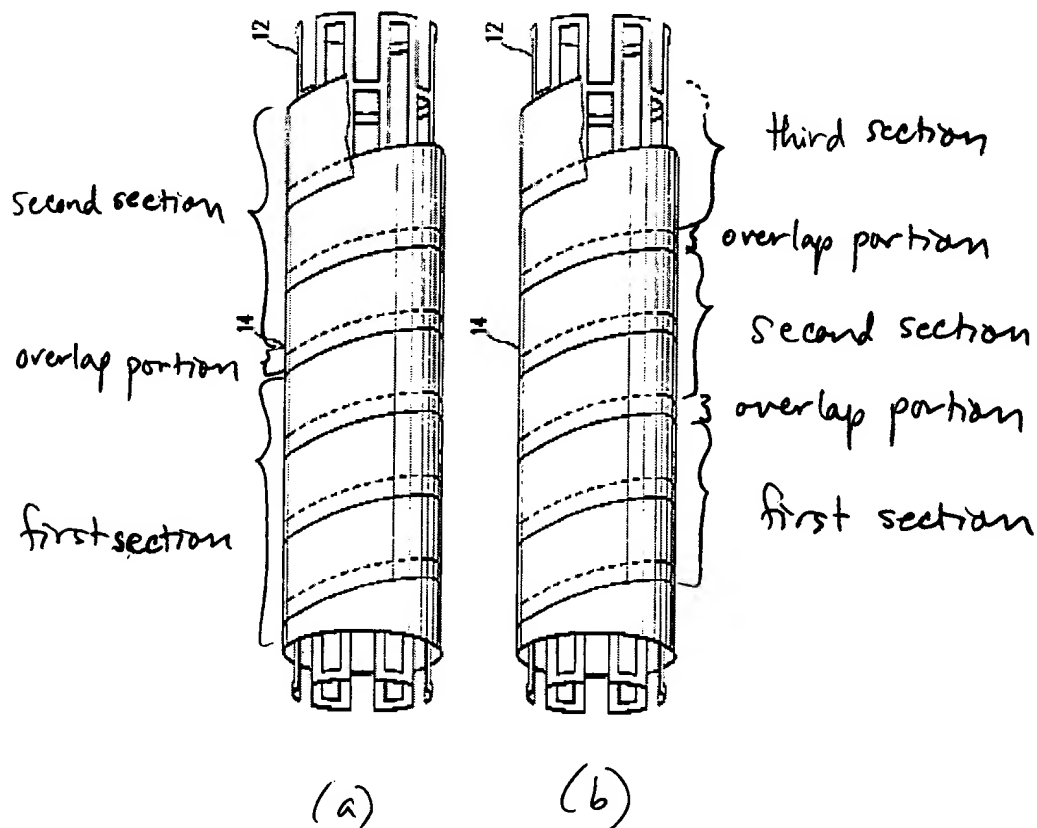
The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily

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published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

9. Claims 1-4, 7-9, 14, 17-23, 26, 27, 29, 33, 36-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Freidberg (USPN 6,254,627).

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claims 1 and 20. See Figure 7(a) below and columns 5-6, lines 63-6 for an intravascular stent (12) having proximal and distal ends and a tubular cover material (14) covering at least a portion of the stent. The cover material has first section and a second section, each with proximal and distal ends, wherein the proximal end of the second section forms an overlap portion with the distal end of the first section. See Figure 7(a) below.



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Claims 2-4 and 21-23, see Figure 7(a) above and column 4, lines 5-8 for cover material distal and proximal ends being attached to the stent and the overlap portion being positioned there-between.

Claims 7-9 and 26, 27 and 29, see Figure 7(a) above. The first three complete wraps is the first section and the next 2+ wraps is the second section, both having proximal and distal ends and both being shorter than the overall length of the stent. The first section and second section overlap and are configured for sliding movement at the overlap portion when the stent is expanded (column 6, lines 1-6).

Claims 14 and 33, see column 4, lines 5-7 and columns 5-6, lines 63-6.

Claims 17-18 and 36-37, see Figure 7(b) above. The first two complete wraps is the first section, the next two complete wraps is the second section, and the next 1+ wrap is the third section. Between the sections is an overlap section, so that there is more than one overlap portion along the stent.

Claims 19 and 38, see column 4, lines 32-36 for cover material being within specified thickness range.

Claims 39 and 40, see column 4, lines 14-27.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claims 15 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freidberg.

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claims 1 and 20, but is silent to the additional limitation of the cover material being attached to the stent by an adhesive, as required by claims 15 and 34.

Freidberg discloses that the cover material (jacket) may be secured to the stent by any suitable means (column 4, lines 5-6) and securing the sides of the stent cover together is done by mechanical means that are old and well known in the art, including adhesive bonding (column 5, lines 35-37). Therefore, it would have been obvious to one of ordinary skill in the art to use adhesive bonding to attach the cover material to the stent by an adhesive.

12. Claims 16 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freidberg in view of Sogard et al. (USPN 6,139,573).

Freidberg discloses a jacketed stent assembly comprising an expandable stent jacketed with a cylinder of biocompatible, non-thrombogenic expandable material with all the elements of claims 1 and 20, but is silent to the cover material being made from ePTFE, what Examiner interprets as PET or polyurethane, as required by claims 16 and 35. Sogard et al. discloses a conformal laminate stent device with a cover material made of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. It would have been obvious to one of ordinary skill in the art to make the

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biocompatible, non-thrombogenic expandable material of Freidberg of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. See column 2, lines 40-45.

Response to Arguments

13. Applicant's arguments with respect to claims 1-4, 7-9, 14-23, 26-27, 29 and 33-40 have been considered but are moot in view of the new ground(s) of rejection.

14. Applicant's arguments filed 6/14/02 have been fully considered but they are not persuasive with respect to Freidberg '627. Applicant argues that unlike Freidberg, applicant's invention is not formed by wrapping a single ribbon of tissue around the entire length of the unexpanded stent. Examiner would like applicant to note that the current claims are product claims, wherein patentable weight is given to the structural limitations of the elements and not to how the structural elements are formed. Even though applicant does not use a single ribbon wrapped around the length of the stent, the product of Freidberg does meet all claimed structural limitations of the above-indicated claims.

15. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., two *separate* sections) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

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16. The word "section" is defined by Webster's II New Riverside University Dictionary to be: "a part or piece of something; portion". A section does not require that it be separate from the whole. Therefore, the first and second sections can be interpreted to be any arbitrary portions of the tubular cover that meet the limitation of the proximal end of the second section forming an overlap with the distal end of the first section. This is clearly shown by Freidberg, as indicated in Figure 7(a) above.

17. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the motivation to combine references is in the reference itself. It would have been obvious to one of ordinary skill in the art to make the biocompatible, non-thrombogenic expandable material of Freidberg of ePTFE in order to provide a surface that is inherently resistant to adhesive bonding, which imparts a natural anti-thrombogenic characteristic to the surface to the cover material. As stated above, this is clearly taught in column 2, lines 40-45 of Sogard et al.

Conclusion

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Urmi Chattopadhyay whose telephone number is (703) 308-8510 and whose work schedule is Monday-Friday, 9:00am – 6:30pm with every other Friday off. The examiner's supervisor, Corrine McDermott, may be reached at (703) 308-2111. The group receptionist may be reached at (703) 308-0858.

Should the applicant wish to send a fax for official entry into the file wrapper the Group fax number is (703) 305-3590. Should applicant wish to send a fax for discussion purposes only, the art unit fax number is (703) 308-2708.



Urmi Chattopadhyay
Art Unit 3738



David H. Isabella
Primary Examiner

uc
September 30, 2002